UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,221	01/02/2004	Keneth K. Cyr	CRNI.111422	6658

46169 7590 12/22/2008

SHOOK, HARDY & BACON L.L.P.
Intellectual Property Department
2555 GRAND BOULEVARD
KANSAS CITY, MO 64108-2613

EXAMINER	
SEREBOFF, NEAL	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
12/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,221	CYR ET AL.	
	Examiner	Art Unit	
	NEAL R. SEREBOFF	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9-12,14-17 and 19-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9-12,14-17 and 19-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/2008 has been entered.

Response to Amendment

2. In the amendment dated 10/27/2008, the following has occurred: Claims 1, 10 and 19 have been amended; Claims 6, 8 and 18 have been canceled.

3. Claim 13 has been previously canceled.

4. Claims 1 – 5, 7, 9 – 12, 14 – 17 and 19 – 27 are pending.

Notice to Applicant

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1 – 5, 7, 9 – 12, 14 – 17 and 19 – 27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

8. Regarding claims 1 – 5, 7 and 9, the claims appear to be software per se without any structural requirements. Since a computer program is merely a set of instructions capable of

being executed by a computer, the computer program itself is not a process and USPTO personnel should treat a claim for a computer program, without the computer-readable medium needed to realize the computer program's functionality, as nonstatutory functional descriptive material. (MPEP §2106.01)

9. Claims 10 – 12, 14 – 17 and 19 – 27 are rejected under 35 U.S.C. 101 based on Supreme Court precedent, and recent Federal Circuit decisions, a § 101 process must (1) be tied to a machine (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. In re Bilski, F.3d , 88 U.S.P.Q.2d 1385 (2008). Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780,787-88 (1876). The process steps in claims (10 – 12, 14 – 17 and 19 – 27) are not tied to a machine nor do they execute a transformation. Thus, they are non-statutory.

10. The Examiner reviewed the originally filed Specification to find machine descriptions.

- Regarding the term hardware as found in the Pre-Grant Publication paragraph 57, "Other Hardware." The term also appears within paragraph 23, "More specifically as shown each care provider may select preferred surgical instruments, anesthesiology drugs or equipment, implants, pharmaceuticals, stethoscope, thermometer or other diagnostic instruments or other supplies, material, ***pharmaceuticals or other hardware***, disposables or other material related to clinical care." (emphasis added) Therefore, the Examiner understands hardware as medically related pharmaceutical supplies and not computer equipment.

- Regarding the term computer as found in the Pre-Grant Publication paragraph 9, "Collective supply activities can not be effectively or comprehensively managed on today's information plat- forms, on the procurement side as well. While many hospitals and other facilities keep computerized records of clinical supplies present and available in given departments, no effective or integrated mechanism exists to order and replenish those supplies on demand." The Examiner notes that the computer is used within the background of the invention and not in relation to the invention itself.
- The term server does not appear.
- A database may be a filing cabinet, a piece of paper, a rolodex or a human brain.
- The supply selections may be on a physical preference card. (paragraph 23)

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 19 – 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The preamble of claim 19 states, "One or more computer-readable media having computer-executable instructions embodied thereon for performing a method for managing clinically related supply procurement according to outcomes, the method comprising." The Examiner notes that neither a computer readable media nor computer executable instructions are

found within the originally filed Specification. Further, the Examiner understands that the pre-amble of claim 19 is considered the intended use of the Applicant's invention and therefore has no patentable weight. The limitation, "computer accessible memory" does not describe how the computer accesses the memory. For instance, a sheet of paper may be scanned. Claims 20 – 27 are rejected for the same reasons as being dependent upon claim 19.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1 - 5, 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The third limitation reads, "showing a comparison of the one ore more patient outcomes from the one or more patients." The Examiner notes that choosing the option of a single patient then makes the comparison of multiple patient outcomes indefinite.

15. Claims 19 – 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of claim 19 ends with the statement, "the method comprising." The preambles of claim 20 – 27 include, "One or more computer-readable media according to claim 19." The Examiner is unsure which statutory class the Applicant intended. The Examiner understands claims 20 - 27 to be process claims and not articles of manufacture claims.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. ***Claims 1 – 5, 7, 9 – 12, 14 – 17 and 19 – 27*** are rejected under 35 U.S.C. 102(b) as being anticipated by Reitberg, U.S. Patent 6,242,463.

18. As per claim 1, Reitberg teaches a system for managing clinically related supply procurement according to outcomes, comprising:

- A first interface to receive patient supply data captured from at least one clinically related site (column 2, line 15 through column 3, line 59), the patient supply data comprising clinical supplies, including a first clinical supply and a second clinical supply (column 2, lines 23 – 35, drug and placebo), used to treat one or more patients (column 2, lines 15 - 22);
- A second interface to receive clinical outcomes data from the at least one clinically related site, wherein the clinical outcomes data describes one or more patient outcomes for the one or more patients that resulted from using the clinical supplies, including the first clinical supply and the second clinical supply, to treat the one or more patients, and wherein a patient outcome is a comparison of a present patient condition relative to an initial patient condition at the time a clinical supply was used to treat a patient (column 2 lines 51 - 64); and
- An analytic engine, the analytic engine communicating with the first interface and the second interface to generate comparative clinical supply reports showing a comparison of the one or more patient outcomes for the one or more patients that resulted from the use of a first clinical supply with the one or more patient outcomes that resulted from the use

of a second clinical supply (column 2 line 60 through column 3 line 2 and column 3, lines 26 - 33).

19. As per claim 2, Reitberg teaches the system of claim 1 as described above. Reitberg further teaches the system wherein the patient supply data comprises at least one of surgical device information, pharmaceutical information, and consumable material information (column 6, line 50 through column 7, line 3).

20. As per claim 3, Reitberg teaches the system of claim 1 as described above. Reitberg further teaches the system wherein the clinically related site comprises at least one of a hospital facility, a research facility and a government facility (column 3, lines 34 – 43, column 5, lines 26 – 44 and column 15, lines 23 – 41) .

21. As per claim 4, Reitberg teaches the system of claim 1 as described above. Reitberg further teaches the system wherein the clinical outcomes data comprises at least one of patient mortality data, patient morbidity data, patient ambulatory data, patient infection data, patient prescription data, patient length of stay data, patient condition data and patient readmittance data (column 7, lines 20 - 26 where the patient condition is a chronic disease).

22. As per claim 5, Reitberg teaches the system of claim 1 as described above. Reitberg further teaches the system wherein the comparative clinical supply reports comprise historical patient outcome comparisons between alternative supply selections (column 6, lines 1 – 14 where the patient pool is used to show comparisons. Further, the exact data shown on a report is considered non-functional descriptive information and therefore has no patentable weight).

23. As per claim 7, Reitberg teaches the system of claim 1 as described above. Reitberg further teaches the system wherein the comparative clinical supply reports comprise projected

patient outcome comparisons based on alternative supply selections (column 5, line 56 through column 6, line 14 where the report shows the projected outcome. Further, the exact data shown on a report is considered non-functional descriptive information and therefore has no patentable weight).

24. As per claim 9, Reitberg teaches the system of claim 1 as described above. Reitberg further teaches the system wherein the comparative clinical supply reports comprise reports on clinical outcomes data broken down according to at least one of clinical procedure type, clinical department, patient condition categories, patient demographic categories, vendor information and cost ranges (column 6, lines 1 – 14 where the patient pool is used to show comparisons. Further, the exact data shown on a report is considered non-functional descriptive information and therefore has no patentable weight).

25. As per claim 10, Reitberg teaches a method for managing clinically related supply procurement according to outcomes, comprising:

- Receiving patient supply data captured from at least one clinically related site (column 2, line 15 through column 3, line 59), the patient supply data comprising clinical supplies used to treat one or more patients (column 2, lines 15 - 22);
- Receiving clinical outcomes data from the at least one clinically related site that describes one or more patient outcomes that resulted from using the clinical supplies to treat the one or more patients (column 2 lines 51 – 64), wherein the clinical outcomes data is patient condition data that includes initial patient condition data and present patient condition data (column 3, lines 62 – 65, where the initial condition is an illness and column 5, line 45 through column 6, line 67 for outcome information); and

- Generating comparative clinical supply reports that show alternative supply-selections for a particular clinical procedure type based at least on the clinical outcomes data (column 2, line 60 through column 3, line 2 and column 3, lines 26 - 33).

26. As per claim 11, Reitberg teaches the method of claim 10 as described above. Reitberg further teaches the method wherein the patient supply data comprises at least one of surgical device information, pharmaceutical information, and consumable material information (column 6, line 50 through column 7, line 3).

27. As per claim 12, Reitberg teaches the method of claim 10 as described above. Reitberg further teaches the method wherein the clinically related site comprises at least one of a hospital facility, a research facility and a government facility (column 3, lines 34 – 43, column 5, lines 26 – 44 and column 15, lines 23 – 41).

28. As per claim 14, Reitberg teaches the method of claim 10 as described above. Reitberg further teaches the method wherein the comparative clinical supply reports comprise historical patient outcome comparisons between alternative supply selections (column 6, lines 1 – 14 where the patient pool is used to show comparisons. Further, the exact data shown on a report is considered non-functional descriptive information and therefore has no patentable weight).

29. As per claim 15, Reitberg teaches the method of claim 14 as described above. Reitberg further teaches the method wherein the historical patient outcome comparisons are based on a combination of at least two supply selections (column 2, lines 23 – 35, drug and placebo).

30. As per claim 16, Reitberg teaches the method of claim 10 as described above. Reitberg further teaches the method wherein the comparative clinical supply reports comprise projected patient outcome comparisons based on alternative supply selections (column 6, lines 1 – 14

where the patient pool is used to show comparisons. Further, the exact data shown on a report is considered non-functional descriptive information and therefore has no patentable weight).

31. As per claim 17, Reitberg teaches the method of claim 16 as described above. Reitberg further teaches the method wherein the projected patient outcome comparisons are based on a combination of at least two supply selections (column 5, line 56 through column 6, line 14 where the report shows the projected outcome. Further, the exact data shown on a report is considered non-functional descriptive information and therefore has no patentable weight).

32. As per claim 19, Reitberg teaches one or more computer-readable media having computer-executable instructions embodied thereon for performing a method for managing clinically related supply procurement according to outcomes, the method comprising:

- Receiving patient supply data captured from at least one clinically related site (column 2, line 15 through column 3, line 59), the patient supply data comprising clinical supplies used to treat one or more patients (column 2, lines 15 - 22);
- Receiving clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies to treat the one or more patients from the at least one clinically related site, and wherein a patient outcome is a comparison of a present patient condition relative to an initial patient condition at the time a clinical supply was used to treat a patient (column 2 lines 51 - 64);
- Generating a comparative clinical supply report based at least on the clinical outcomes data that shows a correlation between at least one clinical supply and the one or more patient outcomes (column 2 line 60 through column 3 line 2 and column 3, lines 26 - 33); and

- Storing the comparative clinical supply report in computer accessible memory (column 6, lines 1 – 14, database).

The Examiner notes that the originally filed specification does not include "computer" within claim 19.

33. As per claim 20, Reitberg teaches the method of claim 19 as described above. Reitberg further teaches the method wherein the patient supply data comprises at least one of surgical device information, pharmaceutical information, and consumable material information (column 6, line 50 through column 7, line 3).

34. As per claim 21, Reitberg teaches the method of claim 19 as described above. Reitberg further teaches the method wherein the clinically related site comprises at least one of a hospital facility, a research facility and a government facility (column 3, lines 34 – 43, column 5, lines 26 – 44 and column 15, lines 23 – 41).

35. As per claim 22, Reitberg teaches the method of claim 19 as described above. Reitberg further teaches the method wherein the clinical outcomes data comprises at least one of patient mortality data, patient morbidity data, patient ambulatory data, patient infection data, patient prescription data, patient length of stay data, patient condition data and patient readmittance data (column 7, lines 20 - 26 where the patient condition is a chronic disease).

36. As per claim 23, Reitberg teaches the method of claim 19 as described above. Reitberg further teaches the method wherein the comparative clinical supply report comprises at least one historical patient outcome comparison between alternative supply selections (column 6, lines 1 – 14 where the patient pool is used to show comparisons. Further, the exact data shown on a report is considered non-functional descriptive information and therefore has no patentable weight).

37. As per claim 24, Reitberg teaches the method of claim 23 as described above. Reitberg further teaches the method wherein the at least one historical patient outcome comparison is based on a combination of at least two supply selections (column 2, lines 23 – 35, drug and placebo).

38. As per claim 25, Reitberg teaches the method of claim 19 as described above. Reitberg further teaches the method wherein the comparative clinical supply report comprises projected patient outcome comparisons based on alternative supply selections (column 5, line 56 through column 6, line 14 where the report shows the projected outcome. Further, the exact data shown on a report is considered non-functional descriptive information and therefore has no patentable weight).

39. As per claim 26, Reitberg teaches the method of claim 25 as described above. Reitberg further teaches the method wherein the at least one projected patient outcome comparison is based on a combination of at least two supply selections (column 5, line 56 through column 6, line 14 where the report shows the projected outcome. Further, the exact data shown on a report is considered non-functional descriptive information and therefore has no patentable weight).

40. As per claim 27, Reitberg teaches the method of claim 19 as described above. Reitberg further teaches the method wherein the comparative clinical supply report comprises a report on clinical outcomes data broken down according to at least one of clinical procedure type, clinical department, patient condition categories, patient demographic categories, vendor information and cost ranges (column 6, lines 1 – 14 where the patient pool is used to show comparisons. Further, the exact data shown on a report is considered non-functional descriptive information and therefore has no patentable weight).

Response to Arguments

41. Applicant's arguments with respect to claims 1 - 5, 7, 9 - 12, 14 - 17 and 19 - 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

42. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Evans, U.S. Patent 6,347,329

Hickle, U.S. Pre-Grant Publication 2002/ 0017299

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. S./
Examiner, Art Unit 3626
12/17/2008

/Robert Morgan/
Primary Examiner, Art Unit 3626